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Subject: OCSPP News for October 6, 2020

OCSPP News Round-Up

TSCA

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Calls Grow To Preserve House-Backed PFAS Measures In FY21 NDAA
Diana DiGangi, Inside TSCA
https://insideepa.com/tsca-news/calls-grow-preserve-house-backed-pfas-measures-fy21-ndaa

Democratic attorneys general (AGs), a bipartisan group of House lawmakers and environmentalists are urging leaders of a congressional conference committee to preserve House-backed legislation addressing per- and polyfluoroalkyl substances (PFAS) in products as they work to resolve differences in their fiscal year 2021 defense bills.

While the groups, in separate letters over the past few weeks, emphasize the need for provisions requiring DOD to remediate PFAS contamination, much of which stems from the use of aqueous film forming firefighting foam (AFFF) containing PFAS, their letters also seek several provisions aimed at eliminating PFAS from AFFF and other products.

"Meaningful PFAS provisions adopted in the House defense authorization bill would address ongoing and legacy contamination from PFAS chemicals, prevent further exposures to our service members and their families, increase transparency and public reporting efforts, and expand critical funding into the development of remediation and disposal

technologies as well as fluorine-free firefighting foams," the bipartisan group of more than five dozen House lawmakers said in a Sept. 18 letter to Rep. Adam Smith (D-WA), Sen. Jim Inhofe (R-OK) and other lawmakers leading the House-Senate conference committee that is negotiating the FY21 National Defense Authorization Act (NDAA).

Although the letters were sent over the past few weeks, Smith told an event hosted by George Mason University Oct. 6 that the bill will not formally enter conference committee negotiations until after the Nov. 3 election.

He said members of the House and Senate hope they can reconcile their respective defense bills for a final vote by the first week of December. However, Smith said, staffers from both the House and Senate have been informally working on the more than 2,000 items in each bill since August.

Significantly, none of the groups weighing in on PFAS issues urges the conferees to include legislation that some lawmakers sought unsuccessfully to include in the House version of the bill, which would amend the Toxic Substances Control Act (TSCA), including a five-year moratorium on new PFAS approvals, a permanent bar on EPA's use of the low-volume exemption to approve new PFAS, and new testing mandates.

However, much of what the groups seek relate to provisions governing the use of PFAS in various products, especially AFFF.

For example, the attorneys general of 19 states plus the District of Columbia called on the lawmakers in an Oct. 5 letter, to include a series of "important" provisions on PFAS that the Democratic House had adopted in its version of the NDAA.

These include provisions barring the Defense Logistics Agency from procuring certain PFAS-containing products, as well as language authorizing $150 million to help the Defense Department (DOD) comply with requirements in the FY20 NDAA requiring it to develop PFAS-free AFFF, as well as PFAS remediation and disposal technologies.

PFAS-Free AFFF

In their letter, the bipartisan group of lawmakers echoed the AGs call but also touted a series of provisions seeking to find a replacement for AFFF containing PFAS, which has been used for decades for military firefighting due to the chemicals' surfactant qualities but has led to widespread contamination around military bases.

This includes language establishing a mechanism for public-private partnerships to facilitate development of a PFAS-free firefighting agent to replace AFFF, requires the National Institute for Standards and Technology and the National Institute for Occupational Safety and Health to conduct a study on the use of PFAS chemicals in firefighting equipment and the risk of exposure faced by firefighters and creates a grant program for additional research and improvements to firefighting equipment.

The House lawmakers also seek to preserve language requiring DOD to survey and report on non-firefighting agent technologies that will help facilitate the phase-out of AFFF and establish a prize program to encourage development of PFAS- free firefighting foam.

The FY20 NDAA generally barred use of AFFF containing PFAS at military installations by no later than Oct. 1, 2024, although it allowed its continued use on board ocean-going vessels and provided for a waiver process for situations where compliance isn't possible.

The law also required DOD to "publish a military specification for a fluorine-free fire-fighting agent for use at all military installations and ensure that such agent is available for use by not later than October 1, 2023."

While the FY20 requirement is intended to prevent further contamination, military officials say that they currently lack safer alternatives that can meet military specifications to ensure the foam extinguishes fires from jet fuel and other flammable sources.

However, DOD officials recently indicated they are optimistic they will be able to meet the legislative deadlines.

The House lawmakers also urge the conferees to language creating an interagency coordinating body for PFAS research "to encourage a whole of government approach to PFAS research."

In addition, dozens of national and local environmental groups sent a Sept. 17 letter echoing much of what the House lawmakers called for, including provisions clarifying that EPA's Toxic Release Inventory rule mandating PFAS reporting requires manufacturers to disclose all PFAS releases over 100 pounds and requires DOD to notify the congressional defense committees when there has been an uncontrolled release of AFFF.

Clean-Up Requirements

While much of what the lawmakers, AGs and environmentalists seek relates to PFAS in products, their top policy priorities seek to encourage remediation of PFAS contamination.

For example, the AGs urge the conferees to include a provision that requires DOD to meet the PFAS standards established in the state where an installation is located when conducting removal or remedial actions at that installation, as well as a provision that would direct DOD to work "expeditiously" on groundwater remediation for PFAS-contaminated sites.

"We strongly support a Congressional mandate that requires DOD to meet the most stringent state standards during site remediation, regardless of whether a state and DOD are able to reach a cooperative agreement," they add.

The letter also requests that Congress go beyond the FY2021 defense authorization bill to designate "at least" PFOA, PFOS, and GenX PFAS as "hazardous substances" under CERCLA, a provision which was proposed as an amendment to the House NDAA, but ultimately did not make it in.

"We previously recommended [this] and still believe" it should be a priority, the attorneys general write. "To start, Congress should direct the EPA to study additional PFAS compounds and, as appropriate, designate additional PFAS compounds as 'hazardous substances' under the Superfund law." -- Diana DiGangi (ddigang@iwpnews.com)

TSCA Scopes For Next 20 Evaluations Seen As Incomplete 'Placeholders'
Maria Hegstad, Inside TSCA
https://insideepa.com/tsca-news/tsca-scopes-next-20-evaluations-seen-incomplete-placeholders

EPA's recently released final scoping documents that will guide how the agency evaluates the next 20 chemicals under TSCA are viewed as incomplete "placeholders," industry and environmentalists say, after officials rejected concerns from a range of stakeholders that its draft scope documents were too vague to comply with TSCA mandates.

"These scopes don't really address many of the questions of how EPA's going to do these evaluations. A lot of issues are just unaddressed here," Robert Sussman, former Obama and Clinton EPA official and counsel to Safer Chemicals Healthy Families, tells Inside TSCA. "I just get the impression that these scope documents are placeholders, they are required by the law but they are not very enlightening. Probably the reason for that is EPA has not really dug into these chemicals and does not have very fixed views on how to evaluate them."

EPA released Sept. 4 final scope documents for the next 20 existing chemicals it is beginning to evaluate as directed in Congress' 2016 rewrite of the Toxic Substances Control Act (TSCA), but the documents generally contain boilerplate language about how the agency will perform the evaluations while omitting details on conditions of use and health endpoints under consideration, among other specifics. In its response-to-comments document released with the final scopes, the agency argues that its approach complies with the law.

EPA did not respond to a request for comment by deadline.

But stakeholders call the documents preliminary and expressed concern if no further details are released before the agency's deadline to release its draft evaluations for public comment and peer review in 2022.

Sussman says one possible reason EPA provided so little information in the final documents is that the systematic review approach EPA developed specifically for the nascent TSCA program has been heavily criticized by agency science advisors, systematic review experts and environmentalists -- and is undergoing peer review by a National Academy of Sciences (NAS) committee.

Systematic review is a relatively new approach to gathering, assessing and integrating chemical and environmental health information. It has been adapted from reviews of evidence-based medicine where it was first developed and its embrace by the agency's toxics and research offices has been intended to increase the rigor and transparency of the chemical evaluations EPA conducts.

While EPA had committed in its TSCA risk evaluation rule to release systematic review protocols for each chemical it plans to evaluate when it releases final scope documents, the agency did not do so when it released the final documents early last month.

"The systematic review side of things is very uncertain," Sussman says. "We have the NAS bearing down on EPA, no recommendations yet but they don't seem to be comfortable with what they are hearing."

Sussman noted that Stan Barone, deputy director of the risk assessment division within EPA's toxics office, told the NAS panel in August that the agency may drop the numerical scoring approach to reviewing individual studies that it used to craft its first 10 risk evaluations, in response to questions from panelists at the committee's last meeting.

"That is the guts of the systematic review process they used," he adds. "They will likely have to start all over again when the NAS report comes out."

Protocol Document

One industry source echoes Sussman, saying it is "possible" that NAS' ongoing peer review and consideration of the TSCA systematic review approach may be delaying release of the individual protocol documents for the 20 chemicals.

"They are obligated [by statute] to get out a final scope document. It's possible they know they have to integrate whatever [advice] they get [from NAS]. They are not technically required to release a systematic review protocol; they are required to release scope and then draft assessment."

Industry sources are also raising concerns about how the final scoping documents addressed the agency's systematic review approach.

For example, the source notes that EPA has added some additional information to many if not all of the final scope documents by adding a component of a systematic review protocol known as a PECO statement. The acronym PECO which describes the population, exposure, comparator, and outcomes of interest in the evaluation.

But the information contained within remains general and the sources say EPA has yet to release any full protocols for the next 20 documents as EPA stated in the draft scope documents it would do before finalizing the scopes.

Instead, the source noted, EPA removed the commitment from the final scope documents.

Many of the documents also contain links to an online database tool called HAWC which EPA is using to conduct aspects of the systematic review, one of the industry sources said.

But the source added that the website is "not populated for any of those 20 chemistries. Maybe they're going to populate that . . . there is some information about the literature search strategy ... We are still definitely hoping to see full systematic review protocols."

While environmentalists raised concerns about the lack of specificity in health endpoints, exposure pathways and susceptible subpopulations that will be included, industry sources noted that EPA's final scope documents failed to include details on conditions of use, including whether a chemical's presence as a byproduct of impurity will be considered.

A second industry source said that on the byproduct and impurity issue, "Generally, EPA's not thinking they need to look at those at small amounts. . . . A lot of clarification [was] added" to EPA's response to comments document.

Comments from environmental groups on the draft scope documents urged EPA to include all conditions of use in its risk evaluations, including the chemicals' presence as a byproduct or impurity. The agency replies in its response to comments document that it has discretion to make such choices in its scoping of the evaluations and will do so on a case-by-case basis.

"EPA intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as a byproduct, impurity or contaminant in another chemical substance that is not the subject of the pertinent scoping. In some instances, it may be most appropriate from a technical and policy perspective to evaluate the potential risks arising from a chemical present as a byproduct, impurity or contaminant within the scope of the risk evaluations for the chemical substance itself," the agency replies in its Sept. 4 response to comments document.

"In other cases, it may be more appropriate to evaluate such risks within the scope of the risk evaluation for the separate chemical substances that bear the byproduct, impurity or contaminant. In still other cases, EPA may choose not to include a particular byproduct, impurity or contaminant within the scope of any risk evaluation, where EPA has a basis to foresee that the risk from the presence of the chemical substance would be de minimis or otherwise insignificant," the agency adds.

Conceptual Models

The second industry source says another issue in the final scoping documents is "the coordination between conditions of use and the conceptual models listed" for individual chemicals," adding that the conceptual models included in the final scope documents are "still fairly general."

As one example, the American Chemistry Council's formaldehyde group sought clarification on the draft formaldehyde scope document over whether the scope will include automotive applications. The draft scope document focused on using the ubiquitous chemical as an intermediate or in formulation, but then lists applications to be considered including plastics and foams that can be used in automotive.

"That level of specificity is not included in many of the scope documents," the first industry source said, adding that EPA in its response to comments document -- though not clearly addressed in the final scope -- provided "a specific answer on formaldehyde that they will be looking at automotive" applications.

In another example, environmentalists questioned what appeared to be EPA's decision to exclude oral exposures in many scenarios in the draft scope documents for the 20 chemicals, and urged the agency to reconsider this exposure route for workers; consumers, particularly children; and the general population. EPA responds by indicating that it will consider these exposures when it has data to support doing so.

"EPA acknowledges that oral exposures are a potential route for workers and agrees that hand-to-mouth and ingestion of dust particles can be sources of occupational oral exposure. EPA has identified chemicals during the scoping phase that will be evaluated for this route based on their physical-chemical properties. However, EPA does not currently have a methodology for quantitatively assessing occupational oral exposure. As described in the draft scope documents, EPA

will consider oral exposure on a case-by-case basis considering all reasonably available data and information," the agency replies.

"The consumer exposure routes as presented in each of the scope documents are dependent on the chemical, the physical-chemical properties and the corresponding conditions of use," EPA continues. "As the commenter noted, chemicals such as TBBPA and TCEP are expected to be in articles and therefore present an oral route of exposure, as identified in the consumer conceptual model. Should data or information be presented through public comment regarding other chemicals' presence in articles that could be mouthed by children, EPA will adjust the respective conceptual models for the risk evaluations to include the oral route of exposure for the risk evaluations." -- Maria Hegstad (mhegstad@iwpnews.com)

States Seek To Strengthen Bill Barring Chemicals In Packaging Materials
Diana DiGangi, Inside TSCA
https://insideepa.com/tsca-news/states-seek-strengthen-bill-barring-chemicals-packaging-materials

State environmental regulators are seeking to strengthen proposed model legislation seeking to bar the use of per- and polyfluoroalkyl substances (PFAS) and phthalates in packaging materials, calling for changes that would toughen the proposed bans while also opening the door for some flexibilities.

In recently released comments, states including Connecticut, Minnesota, New Hampshire and New York, urged the Toxics in Packaging Clearinghouse (TPCH), the nine-member state group that drafted the model legislation, to make a series of changes that would have the effect of strengthening the draft version.

For example, Minnesota's Pollution Control Agency (MPCA) urged the group in Aug. 24 comments to add a PFAS definition that is "sufficiently comprehensive," while also calling for phasing out the "intentional use of PFAS chemicals in all packaging and packaging components within a short and defined timeframe," as well as "the use of PFAS as a manufacturing or processing aid in packaging."

Minnesota and several of the other states that commented also backed -- or urged TPCH to expand -- the model legislation's draft criteria that states regulators can use to regulate additional chemicals in the future or recommend their regulation to state legislatures, saying such provisions will help prevent releases in the future.

"The MPCA supports . . . the strong pollution prevention approach taken for PFAS, ortho-phthalates, and chemicals that may be added in the future with the criteria and process established in Section 6. This approach will reduce the loading of PFAS and other chemicals in regulated systems, such as stormwater; municipal and industrial wastewater; and solid waste, recycling, and organics composting facilities," MPCA said.

"It will also reduce releases from all types of manufacturing where PFAS and other chemicals are made, handled, or used, and other direct releases to the environment, for example, through littering of packaging materials that may contain these substances," MPCA said.

Such comments came in response to TPCH's draft model bill released earlier this year that sought to add PFAS and phthalates to the group's existing model legislation -- adopted by the nine-member states as well as 10 others -- that already bars the "intentional use" of cadmium, lead, mercury, and hexavalent chromium in packaging.

The proposal marks just the latest effort by states to clamp down on PFAS and other chemicals in packaging and other materials. For example, New York's legislature earlier this year approved legislation banning PFAS as an "intentionally added chemicals" in food packaging, though Gov. Andrew Cuomo (D) has yet to act on the measure.

But such proposals are drawing stiff opposition from the chemical industry, which is especially concerned that many of the states' policies seek to regulate the chemicals in groups, without regard for structural and other differences in the thousands of substances in the class.

"Painting all chemicals that share some generic name with a broad brush makes for bad policy that can prevent consumers from accessing important, safe and beneficial products they need," ACC said in Aug. 24 comments on TPCH's proposed model legislation.

As a result, ACC says, it is concerned that the proposed model legislation will lead to "flawed regulations -- and chemical assessments based on these regulations -- and may create public confusion, cause unwarranted alarm, and product de-selection. All of which serves to further erode public confidence in existing chemical management programs," the group's comments say.

'Incidental' Amounts

But the states pushed back on such criticisms. For example, New York's Department of Environmental Conservation (DEC), Connecticut's Department of Energy and Environmental Protection (DEEP) and New Hampshire's Department of Environmental Services (DES) questioned TPCH's language that would have allowed production, sale or distribution of packaging materials containing PFAS and phthalates in "incidental" amounts -- defined as 100 parts per million by weight.

DEC called the language "subjective and problematic," writing that regulators would prefer a "blanket prohibition" due to the fact that the addition of PFAS during manufacture is the issue at hand, it said in its June 8 comments.

"While in PFAS, for example, there could be naturally occurring fluorine compounds present -- these are not intentionally added," said NYSDEC. "The Department believes the supply chain should have full control over what is intentionally added to packaging during its manufacture."

Instead of the current approach, DEC recommended that TPCH set a standard to limit the presence of the chemicals from naturally occurring or other "unintentional sources."

"While the Department feels the 100 ppm exceedance limit for an incidental presence is high (when states are looking at levels at part per billion or trillion level in soil, compost, etc.), we do find value in setting a threshold to limit the amount present from unintentional sources (i.e., naturally or present through recycling feedstock) that is consistent with industry groups and certification bodies," the state said.

DEC also asked for the model legislation to provide exemptions for phthalates and PFAS, as acceptable substitutes have not yet been found for every single use of these chemicals in packaging. "Many companies have turned to PFAS other than PFOA and PFOS, and while we want them to stop using all PFAS, the Department is concerned there might not be a practicable alternative at this time," officials said.

"The existence of the ability to apply for an exemption does not guarantee approval," they added.

New Hampshire's DES echoed New York's call, asking why PFAS were not included in the bill's exemptions. "Could there be unique cases where specific PFAS are the only feasible choice given the application and other considerations?" officials wrote in their undated comments.

DES also asked TPCH to justify its selection of the 100-ppm standard, asking if it was based on a human health assessment, technologically achievable limit, or a practical limit of computation.

But there were also disagreements among the states. For example, New Hampshire raised concerns about the lack of available substitutes for PFAS, saying that the existing broad definition could lead industry to take issue with it, as ACC and other industry groups already have.

"Depending on how broad the definition ultimately is, there is a risk of regrettable substitutions," said NHDES. "By eliminating an entire class of compounds, switching to alternative and perhaps entirely new chemistries is possible. How does the Clearinghouse plan to track new technologies?"

Similarly, MCPA appeared to be at odds with New York's DEC on the issue of exemptions, writing that "providing no exemptions or exceptions that could result in continuing use of 'current' PFAS chemicals and/or substitutions with 'new' PFAS chemicals that are not as well understood as those currently in wide use" would spur research and innovation to develop safe PFAS alternatives. -- Diana DiGangi (ddigangi@iwpnews.com)

California to consider Prop 65 listing for 22 substances

Chemical Watch

https://chemicalwatch.com/162988/california-to-consider-prop-65-listing-for-22-substances

California regulators will meet in December to discuss the possible developmental and reproductive toxicity (DART) of nearly two dozen chemicals and chemical groups, potentially setting the substances up for listing and notification requirements under the state's right-to-know scheme, Proposition 65.

The Developmental and Reproductive Toxicant Identification Committee (Dartic) will meet on 11 December to advise California's Office of Environmental Health Hazard Assessment (Oehha) on the prioritisation of the chemicals for potential Prop 65 listings, Oehha said on 2 October. It also said it will accept public comments on the 22 substances until 16 November.

No listing decision will be made at the December meeting, Oehha said. But it would announce any such judgement in a separate notice issued afterwards.

The 22 substances and chemical groups Dartic will discuss are:

- benzophenone-3;
- bisphenol S;
- diazinon;
- diethyl phthalate;
- domoic acid;
- glyphosate and its salts;
- manganese;
- titanium dioxide nanoparticles;
- vinpocetine; and
- zearalenone.

Neonicotinoid pesticides

- acetamiprid;
- clothianidin;
- imidacloprid; and
- thiamethoxam.

Parabens

- butyl paraben;
- isobutyl paraben;
- methyl paraben; and
- propyl paraben.

Per- and polyfluorinated substances (PFASs)

- perfluorodecanoic acid (PFDA);
- perfluorohexanesulfonic acid (PFHxS);
- perfluorononanoic acid (PFNA); and
- perfluoroundecanoic acid (PFUnDA).

Glyphosate already listed

One substance up for discussion, glyphosate, is already on the Prop 65 list, based on a determination from the WHO's International Agency for Research on Cancer (Iarc) that the herbicide is 'probably' carcinogenic to humans.

California is currently appealing a June court decision that blocked the state from requiring a Prop 65 notice warning of its carcinogenicity, saying the Iarc determination is at odds with the findings of other authoritative agencies, including the US EPA.

A new listing for glyphosate based on potential developmental and reproductive toxicity could result in new Prop 65 requirements, based on the DART assessment.

EPA gives itself more time to consider request for TSCA risk management procedural rule

Terry Hyland, Chemical Watch

https://chemicalwatch.com/162614/epa-gives-itself-more-time-to-consider-request-for-tsca-risk-management-procedural-rule

Five industry groups that asked the US EPA to create a rule to govern the risk management process under TSCA will have to wait a little longer for a response, after the agency said their request was "not a valid petition" under the federal chemicals law.

The decision from the EPA means a proposed rulemaking to set up a risk management framework for TSCA is not likely until next year at the earliest.

The request for a rule – submitted in June by the American Coatings Association, the US Chamber of Commerce, the National Association of Home Builders, the National Association of Manufacturers (NAM) and the Toy Association – "is not a valid petition under TSCA section 21", the EPA said in a reply letter. Section 21 is the law's citizen petition provision, under which anyone can ask the agency to initiate, amend or repeal a rule under the law. The TSCA provision gives the EPA 90 days to respond, meaning the agency would have had to issue a decision by the end of August.

"Section 21 does not provide a means for petitioning EPA to initiate a procedural rule" that would govern the TSCA process, the EPA replied in its 28 July letter. Instead, the agency said it would consider the request for a procedural rule under another federal law – the Administrative Procedures Act (APA). Unlike TSCA, the APA only requires the agency to make a determination within "a reasonable time".

This "gives the EPA more time", Rachel Jones, NAM's vice president of energy and resources policy, told Chemical Watch. She said she is optimistic the EPA will eventually move ahead on a rule to manage the risk management process under TSCA. But, Ms Jones added, it is unlikely there would be a proposal before next year.

A spokesperson for the EPA confirmed on 2 October that the agency is considering the petition under the APA, but that the agency has not yet made a decision on the industry groups' request.

Alexandra Dunn, the EPA's assistant administrator for the Office of Chemical Safety and Pollution Prevention (OCSPP), previously told Chemical Watch that the timing of the petition for a TSCA procedural rule presented challenges.

The EPA recently finalised a TSCA risk evaluation for HBCD, the third to be completed under the amended statute. It hopes to finalise seven more evaluations by the end of this year and it recently set out the scope of review for the next set of 20 chemicals to be reviewed.

Control over citizen petitions

There may be another reason the EPA chose to reject the petition under TSCA, Ms Jones said. Agencies have an internal desire to maintain control over the statutes they administer, she said.

Excluding a request for a procedural rule from TSCA's citizen petition provision preserves the agency's control over what the section 21 petition process looks like and "keeps it more narrow", Ms Jones said.

The agency is already in federal court in California defending its authority over the TSCA section 21 process. In that case, a number of health and environmental organisations are hoping to get the EPA to use section 6 of TSCA to prohibit the addition of fluoride to drinking water. A court order forcing the agency to act could encourage more groups to take advantage of TSCA's citizen petition provision.

'High priority' for downstream users
In their petition, the industry groups said a rule governing the TSCA risk management process could help to organise and direct the different options the EPA has to address any identified unreasonable chemical risks, as well as outline how the EPA takes alternative substances into account.

The five organisations, which together represent hundreds of thousands of US businesses and downstream chemical users, also said a rule guiding the risk management process should clarify that uses not deemed to pose an 'unreasonable risk' would be exempt from regulation.

The EPA "already has started to announce some pieces" of the risk management process, Ms Jones said. The agency has been reaching out to different groups that could be affected by TSCA rules restricting the uses of certain chemicals and holding forums to talk about the risk management process. "They've started to operationalise a lot of the things we asked for," Ms Jones said.

This is a "high priority" for downstream users because, while few NAM members make chemicals, "almost all of them use chemicals", she said. It is important to be able to communicate how chemical risks can and will be managed, Ms Jones said, especially for those, like downstream users, who are "removed from the process of making chemicals".

NMP producers ask US EPA to allow public comment on late submitted studies
Jon Kelvey, Chemical Watch
https://chemicalwatch.com/162737/nmp-producers-ask-us-epa-to-allow-public-comment-on-late-submitted-studies

A coalition of N-Methylpyrrolidone (NMP) producers has asked the US EPA to allow two more months for public comment and scientific peer review for two reproductive toxicity studies the group submitted to EPA in April, months after the agency had released a draft TSCA risk evaluation for the substance.

The new information should be open "to public comment in the interest of sound public policy", the NMP Producers Group said in a letter to the EPA, dated 24 August. "This important new information was not available to the public at the time the comment period was open for the draft risk evaluation; nor was it available to the Science Advisory Committee on Chemicals (Sacc) at the time of its peer review of the draft risk evaluation", the group said in the letter, which was published in the NMP Federal Register docket on 30 September.

If the agency opens a 60-day comment period on the two studies as the NMP Producers Group requests, it would further delay the final risk evaluation for NMP, one of the first ten chemicals to be evaluated under amended TSCA. The final risk evaluations for all ten substances were due in June, but only three evaluations have been finalised thus far. The EPA has said it expects to finalise the remaining seven evaluations by the end of the year.

An EPA spokesperson reiterated that the NMP risk evaluation will be among the final evaluations published this year, but did not address the NMP Producers Group request.

"EPA has reviewed these studies using our systematic review process and is in the process of incorporating them as appropriate into the final risk evaluation to be published later this year," they said.

A handful of NGOs had opposed the EPA even accepting the studies, both because it could delay the final risk evaluation, and because the studies could change the outcome of that evaluation. For that reason, lead senior scientist at the Environmental Defense Fund (EDF), Richard Denison, said allowing comment on the studies alone is not sufficient. The EPA would need to issue an entirely new draft risk evaluation and put that document out for comment.

"It's clear that the NMP group wants them included because they feel it will change the outcome of the risk evaluation", he said. "So we need to comment on a redrafted risk evaluation that addresses how these studies have been reviewed by EPA, as well as how they have been analyzed and integrated".

A spokesperson for the NMP Producers Group declined to comment in detail, saying the group's letter to the EPA spoke for itself. They also noted that the EPA has not yet responded to the group's request.

A similar case

The NMP Producers Group said that public comment limited to the two newly added studies is in line with the process the EPA used regarding studies incorporated into the risk evaluation of Pigment Violet 29 (PV29), which had not been publicly available due to claims of confidentiality. "In that case, EPA reopened the comment period on the draft risk evaluation for the substance in light of the newly released studies", the group said.

But Denison argued that the release of the study information in the PV29 risk evaluation was of a different type than the studies submitted for NMP. "One of the differences there is that EPA just kept putting out more detail about the data they already used; they were not brand new studies", he said. "They had originally only provided a robust summary, then provided a more full version of the underlying report".

A history of confidentiality concerns

The draft risk evaluation of NMP was released in November 2019, and mentioned the two studies, but did not incorporate them due to confidentiality concerns from the NMP Producers Group. The group eventually changed course and submitted the full studies to EPA in April. The EPA added the studies to the draft risk evaluation docket in July.

Mr Denison said the fact the agency published a letter submitted in August on 30 September could indicate it is close to making a decision.

The NMP Producers Group consists of Ashland, BASF Corporation and the Lyondell Chemical Company.

This story was updated on 5 October to add comments from the EPA in the fourth and fifth paragraphs.

TSCA Cost Sharing Consortias Are Broken Due to EPA Rule – Can They Be Fixed?

Martha Marrapese, JD Supra, Wiley Rein LLP

https://www.jdsupra.com/legalnews/tsca-cost-sharing-consortias-are-broken-96149/

Under the EPA fee rule for TSCA (40 C.F.R. § 700.45), manufacturers (including importers) of chemicals undergoing risk evaluation are subject to the TSCA fee of $1.35 million. Following publication of a preliminary list of fee payers in January 2020, companies who make or import the next 20 chemicals to undergo risk evaluation in any quantity were required to identify themselves to EPA. Initially there were no exemptions from this requirement, so companies who imported the next 20 chemicals in any quantity, even as impurities and in articles and de minimis amounts in mixtures, had to sign up to pay the fee. EPA subsequently offered enforcement discretion to companies who import these chemicals in articles, or when they are present as impurities and byproducts.

The deadline for self-identifying to EPA was May 27th. On September 4th, EPA issued the final list of fee payers, as well as the final scopes for the 20 chemicals. Fee payments are now due within 120 days of publishing the final scope of an EPA-initiated risk evaluation (by January 2021). Until November 4, industry can notify EPA of the formation of consortiums. Companies that do not join consortia will be invoiced by EPA for their per capita (equal) share separately. The agency plans to begin invoicing for the fees after this 60 day period; due to the public health emergency, EPA is reportedly exploring options for payment flexibility.

As downstream customers who happen to import these chemicals are fast learning, the major manufacturers and importers of the next 20 chemicals have no incentive to enter into consortia agreements that apportion the fee payment based on market share. Companies are expected under EPA's rule to pay no more than equal amounts of the total fee

split among all of the participating companies. This means that a company who imports 6 pounds of a chemical is on the hook for the same amount as a company who manufactures 60 million pounds. Right now, these companies are facing fee payments on the order of $50,000 to $115,000.

It is important to note that companies could not choose to stop making or importing these chemicals in May to avoid these fees. By rule, the cutoff date is when EPA commences prioritization for the chemical, which happened for the next 20 chemicals in March 2019. 40 C.F.R. § 700.45(b)(5)(ii) and (b)(6)(i). EPA did not publish a preliminary list of manufacturers and importers subject to the risk evaluation fees until January 2020. Since EPA does not announce which chemicals it plans to prioritize in advance, the current rule does not provide a reasoned opportunity for importers of small amounts of these chemicals to avoid these fees by finding a substitute. In fact, the rule encourages just the opposite and locks companies into continuing to use these chemicals over the next 5 years to the greatest extent possible, to justify having to pay the fee. EPA was concerned about companies gaming the system by leaving the market and then re-joining after it's too late to be charged a fee. Several commenters during the rulemaking expressed the same concern, and directed EPA to look at the process for reimbursement that already exists in section 4 of TSCA and adopt a similar procedure. EPA declined, and in so doing created a process that offers no immediate incentive to find a substitute, and puts an undue and costly regulatory burden on downstream users.

It doesn't make sense for companies to join coalitions under these terms if it would only result in paying more based on having a larger share of the market. As a result, for the importer of 6 pounds of one of these chemicals in a mixture, there is no realistic alternative right now to having to pay a per capita share of the fee to EPA.

EPA plans to issue a proposed rule to amend the fee rule and eliminate fees in certain cases, such when they are used strictly for R&D, and when present in imported articles and as impurities or byproducts. In other words, the proposal is reportedly slated to include the traditional suite of exemptions found in 40 C.F.R. § 720.30. We expect to see the proposal before the end of the year. It's worth noting that there are no quantity limits associated with being excused from fees if you qualify in one of these categories, and that these conditions of use are still within the scope of the risk assessments.

However, it's not clear that EPA plans to include an exemption for de minimis quantities in mixtures. We don't think the suppliers of chemicals that undergo risk evaluation are likely to advocate for a de minimis exemption for imported mixtures, due to concerns about shrinking the fee base. EPA may share this same concern. It is likely that the major manufacturers and importers will put more emphasis on advocating for greater flexibility in fee sharing.

Historically, it was common practice for the manufacturers of chemicals that have undergone testing or evaluation by EPA have agreed to share costs amongst themselves according to production volume without involving the customer base directly. Through the leadership exercised by these consortia, the customer base was traditionally released from payment obligations of TSCA, as in the case of testing programs conducted under section 4. As we already noted, the EPA rule is disincentivizing suppliers from following this example. The way EPA has structured the rule, anyone who wants to manufacture/import a chemical undergoing risk evaluation is most likely going to wind up paying a per capita share. U.S. antitrust law contemplates that each competitor will try to minimize its own costs and no company is required to accept a higher cost in order to provide a benefit to a competitor. There is no incentive in the EPA rule for companies to do other than achieve that result (with a break for small businesses). As a result, the rule works against forming consortia that allow alternative arrangements based on production volume, since taking a per capita share will cost less for the companies with larger volumes than anything the consortium can otherwise devise. Some commenters tried to alert EPA that the ability to pay a smaller fee could affect consortia decision-making by relatively large producers. A per capita fee consortium is the natural effect of the regulations, and companies are acting in their own best interest under the rule.

Since the cut-off date for not having to pay these fees has passed, and no exemptions are currently available for de minimis quantities in imported mixtures, the incentive or benefit associated with engaging with the consortium remains primarily in the technical expertise they offer to engage with EPA during the risk evaluation. However, it's not clear what additional cost beyond the initial fee that would involve. Is there any incentive for companies to apportion those costs on anything other than a pro capita basis either?

In short, companies are left with having to try and predict what chemicals EPA will commence for prioritization in the future, which is virtually impossible to do. Alternatively, these companies could plan to strongly advocate for an exemption for de minimis quantities in mixtures. In general, it may prove difficult to apply any changes to the rule retroactively. Even so, there is still a chance to change things for the better in the future to make the system fair.

There is a general sense inside the Beltway that a number of importers have inadvertently or intentionally failed to report on these first 20 chemicals, and there are many companies who are facing large invoices from the government disproportionate to their use. This promises to be an active area during the upcoming rulemaking process.

EPA Science Panel Will Impact Asbestos Regulations

Clifford V. Pascarella II, The National Law Review CMBG3 Law
https://www.natlawreview.com/article/epa-science-panel-will-impact-asbestos-regulations

On October 1, 2020, the EPA announced the nominees for the approximately 15 additional spots on the TSCA Scientific Advisory Committee on Chemicals ("SACC"). SACC is a group of experts chosen by the EPA to "provide independent scientific advice and recommendations to the EPA on the scientific basis for risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated under the Toxic Substances Control Act (TSCA)". Currently, there are 16 SACC members and there are 10 additional SACC ad hoc Peer Reviewers. The publicly available list of all the nominees for the EPA science panel is provided below, and EPA is accepting comments on all nominees until October 30, 2020.

William J. Adams Udayan Apte Chris H. Babcock
Marissa G. Baker Aaron Barchowsky Richard B. Belzer
Sol Bobst Robert Budinsky Michael J. Carvan III
Christine F. Chaisson Jane E. Clougherty George P. Cobb
John Joseph Curley Jamie C. DeWitt Michael L. Dourson
Katherine Fallace David V. Gauvin Daniel A. Goldstein
Elliot B. Gordon Julie E. Goodman Brian D. Hardin
Nitin M. Hate' Wendy J. Heiger-Bernays Maryann Hoff
Huixiao Hong Muhammad M. Hossain Jon A. Hotchkiss
Vijayavel ("Vigay") Kannappan Agnes Karmaus Michael C. Kavanaugh
Maureen K. Little Mark A. Maddaloni Carmen Messerlian
Grover P. Miller Franklin L. Mink Peter Moleux
Lisa M. Nespoli Mary Ann Ottinger Heather B. Patisaul
Andrew W. Pawlisz Laura M. Plunkett Gloria B. Post
Jennifer Przybyla David M. Reif Mark Gregory Robson
Paul Rosenfeld Sarah E. Rothenberg Diego Rua
Marc J. Rumpler Ivan Rusyn Darius D. Sivin
Carr J. Smith Gavin P. Smith Jordan N. Smith
James L. Stevens David C. Volz Katherine Von Stackelberg
Charles V. Vorhees Chris D. Vulpe Jeffry K. Wickliffe
Hong Zhuang

SACC will have significant influence on EPA's Risk Evaluations under TSCA, including its ongoing Risk Evaluation for Asbestos. In March 2020, EPA released a Draft Risk Evaluation for Asbestos ("DRE") that drastically narrowed the gap between the Lifetime Unit Risk (UB) of chrysotile and the amphibole asbestos minerals (e.g., crocidolite, amosite, tremolite, actinolite, anthophyllite). Following publication of the DRE, EPA received comments from more than 60 parties compromised of researchers, medical experts, trade organizations, and asbestos litigation groups. Significant criticism of the DRE has been focused on new threshold standards for exposure to chrysotile asbestos that contradict long-settled conclusions by the scientific/medical community that chrysotile is unequivocally less potent than amphibole asbestos. If finalized in its current form, the DRE could be cited by plaintiffs in response to defendants' low-dose chrysotile defenses.

The current SACC members have already issued 103 recommendations concerning the DRE. Most notably, it recommended deriving one Inhalation Unit Risk (IUR) for all types of asbestos, not just for chrysotile. This is significant given the long-established opinion of the medical/scientific community that chrysotile is less potent than the amphibole asbestos minerals. Setting one IUR may create a false impression that all the asbestos minerals are equipotent. SACC also recommended the removal of any statements in the DRE describing chrysotile as "biologically inert." This will further impact chrysotile defenses as medical experts have previously testified that low dose chrysotile exposure is generally insufficient to cause diseases. However, SACC also recommended that EPA re-evaluate its data and modeling as well as collect additional data to support certain conclusions regarding the risks associated with chrysotile. This recommendation is in conjunction with SACC's position that EPA should re-title the DRE to specify that it is focused on chrysotile or postpone issuing a final Risk Evaluation until a larger evaluation of asbestos can be completed. In totality, SACC's recommendation illustrates an awareness that chrysotile should be the focus of the DRE.

EPA must modify agrochemical regulatory process to protect bees
Harry Siviter, The Hill
https://thehill.com/opinion/energy-environment/519772-epa-must-modify-agrochemical-regulatory-process-to-protect-bees

America does not have a great record of licensing of dangerous chemicals used in agriculture. There are 72 pesticides that can be used in the U.S. that have been banned from agricultural use in the European Union because of possible risks to humans and wildlife.

Food production in the U.S. and around the world is dependent on pollination provided by bees and other insects. In fact, it is thought that 1 in 3 mouthfuls of food we eat are dependent on insect pollination. Increasing evidence of bee declines across the U.S. will, therefore, have environmental and economic consequences. We have both selfish and moral obligations to try and help our important pollinators.

Despite this, the Environmental Protection Agency, following instructions from the Trump administration, continues to license new insecticides known to harm bees. One group of insecticides used across the country but is heavily restricted in the EU and Canada is neonicotinoid pesticides. Neonicotinoids are the most commonly used insecticides globally, and in 2014 they made up 25 percent of global insecticide sales. However, evidence of unwanted effects on pollinators led to an agricultural ban on four commonly used neonicotinoids (imidacloprid, thiamethoxam, clothianidin and thiacloprid) in the EU.

Importantly, these bans were put in place because the insecticides have sublethal effects on pollinators such as bees. For example, these insecticides contaminate the nectar and pollen of treated crops where bees and other pollinators feed. Exposure can impair bee foraging, learning and even their ability to fly. They can also reduce bee reproduction, meaning fewer bees in the next generation.

But despite pressure from conservationists and beekeepers throughout America, neonicotinoids have not been banned from agricultural use.

To make matters worse, newly licensed insecticides (such as flupyradifurone and sulfoxaflor) that could potentially replace neonicotinoids also appear to have similar sublethal effects on bees and other pollinators. This clearly demonstrates that even if neonicotinoid use were restricted, other insecticides that are harmful to bees would be used instead.

Moving forward, if we want to protect bees and other insects from the unwanted effects of agrochemical exposure, the EPA must ensure that sublethal assessments of newly developed insecticides on wild bees are mandatory within the regulatory process.

The EPA uses toxicity assessments to determine whether novel insecticides kill bees. Although this is important, a dependency on toxicity assessments fails to assess sublethal effects on reproduction, which is unlikely to be assessed

before licensing, meaning insecticides will be licensed for use without their sublethal effects on bees being known. If a bee dies, it does not contribute to the next generation. If a bee fails to reproduce, it similarly does not contribute to the next generation. On a population scale, there is no difference.

Another issue is that domestic honeybees are used as a model species in the EPA's regulatory process, with less consideration given to native bees. Honeybees are important for pollination, but they are a managed species and not representative of the 4,000 native bee species across the U.S. Wild bees, such as bumblebees and solitary bees, appear to be more vulnerable to agrochemical exposure than honeybees.

Although seldom in the limelight, native bees are essential for the pollination of commercial crops and wildflowers. They also offer a pollination buffer if commercial honeybee stocks decline or if supply problems arise, such as those seen during the ongoing pandemic. Native bee declines will result in us living poorer lives.

EPA gives Oklahoma authority over many tribal environmental issues
Long-term, intensive agriculture is unsustainable. Policies that encourage farmers to reduce chemical use and promote biological control are essential to halt declines in native bees.

Large changes to farming will take time, but the EPA can buy bees more time by modifying the regulatory process to protect bees better. A failure to implement these changes will result in more insecticides being licensed for harmful environmental effects.

EPA Accepting Public Comments for Candidates under Consideration for TSCA SACC Membership
Lynn L. Bergeson & Carla N. Hutton; Inside TSCA Blog
http://www.tscablog.com/entry/epa-accepting-public-comments-for-candidates-under-consideration-for-tsca-s

The U.S. Environmental Protection Agency (EPA) is accepting public comments for all candidates under consideration for membership on the Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals (SACC). Biographies for all candidates are available in Docket ID EPA-HQ-OPPT-2020-0135. When providing comments, EPA states that stakeholders should not submit electronically any information considered to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Comments are due October 30, 2020. EPA will use public comments to assist in selecting multiple members of the SACC over the next year.

EPA anticipates appointing approximately 15 members to the SACC by March 2021. EPA notes that current SACC members are eligible for reappointment during this period. Therefore, the appointments completed by March 2021 may include a mix of newly appointed and reappointed members.

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